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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,641	06/11/2001	Cato T. Laurencin	DRE-0055	2890

26259 7590 10/01/2002

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,641

Applicant(s)

LAURENCIN ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The use of the trademarks LEEDS-KEIO, DACRON and GORE-TEX has been noted in this application. They should be **capitalized** wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

2. Claims 2 and 3 objected to because of the following informalities:
- a. Claim 2, line 3, "support" should be changed to --supported--.
 - b. Claim 3, line 1, "where" should be changed to --wherein--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hlavacek et al. (USPN 4,792,336 as cited in applicant's IDS).

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Hlavacek et al. discloses a braided ligament or tendon implant with all the elements of claim 1. See column 8, lines 55-57 for replacement construct comprising a degradable, polymeric fiber-based (column 4, lines 57-65) braided scaffold (column 5, lines 13-14), which inherently is three-dimensional.

Claim 6, see column 8, lines 55-59 for method of replacing damaged ligament by implanting at the damaged ligament the construct of claim 1.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hlavacek et al. in view of Vacanti et al. (USPN 5,855,610).

Hlavacek et al. discloses a braided ligament or tendon implant with all the elements of claim 2, but is silent to the degradable polymeric fiber-based, three-dimensional braided scaffold being seeded with cells, ingrowth of which is supported by the scaffold. Vacanti et al. teaches a replacement construct comprising a degradable, polymeric fiber-based, three-dimensional scaffold (see abstract, column 3, lines 42-44, column 4, lines 1-25) seeded with cells (column 2, lines 52-53), ingrowth of which is supported by the scaffold (column 3, lines 22-23). Examiner contends that seeding the scaffold with cells, specifically *in vitro*, provides for a more rapid development and differentiation process for the tissue being formed, and it is

clear that cellular differentiation and the creation of tissue specific extracellular matrix is critical for the engineering of a functional implant. Seeding cells onto the scaffold prior to implantation also provides the scaffold with greater strength when the cells proliferate, which allows for the scaffold to endure the *in vivo* forces that act upon it once implanted. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Vacanti et al. to modify the ligament or tendon implant of Hlavacek et al. to seed the polymeric scaffold with cells in order for a more rapid development and differentiation process of the tissue being formed and added strength to the scaffold prior to implantation.

Vacanti et al. also teaches the limitations of claims 2-5, which require the cells be mesenchymal in origin, generate mesenchymal cells and be pluripotent stem cells, respectively. See column 6, lines 35-40 and 50-53. It would have been obvious to one of ordinary skill in the art to modify the implant of Hlavacek et al. by seeding the scaffold with cells that are mesenchymal in origin, say fibroblasts, in order to form a ligament replacement construct or with pluripotent stem cells because they are immunologically inert.

Claim 7, see rejection to claim 2, *supra*, and column 8, lines 55-59 for Hlavacek et al. disclosing the method of replacing a damaged ligament.

7. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al. in view of Hlavacek et al.

Vacanti et al. discloses a method for producing a graft material composed of living cells in a degradable matrix with all the elements of claim 8, but is silent to the scaffold being braided. See columns 6-7, lines 57-18 for harvesting, growing and passaging cells in tissue culture, and

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column 3, lines 42-44, column 4, lines 1-25, column 2, lines 52-53 and abstract for seeding the cultured cells on a degradable, polymeric fiber-based, three-dimensional scaffold. Hlavacek et al. teaches a ligament or tendon replacement construct comprising a degradable, polymeric fiber-based (column 4, lines 57-65), three-dimensional scaffold that is braided (column 5, lines 13-14) in order for the implant to have the desired strength and stiffness in the primary (axial) loading direction. See column 6, lines 39-51. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to make the degradable, polymeric fiber-based, three-dimensional scaffold of Vacanti et al. braided in order to impart the desired strength and stiffness in the primary (axial) loading direction.

Claims 9-11, see column 6, lines 35-40 and 50-53 for specific cells.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay
Art Unit 3738

uc
September 25, 2002



David J. Isabella
Primary Examiner